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**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

MUTUAL PHARMACEUTICAL  
COMPANY, INC., et al.,

Plaintiffs,

-v-

WATSON PHARMACEUTICALS,  
INC., et al.,

Defendants.

Civil Action No.  
3:09-cv-5421 (GEB) (TJB)

**Filed Electronically**

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**DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S RESPONSE  
TO PLAINTIFFS' SUPPLEMENTAL STATEMENT OF DISPUTED  
MATERIAL FACTS**

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Defendant West-Ward Pharmaceutical Corp. (“West-Ward”), pursuant to Local Rule 56.1(a), responds to Plaintiffs’ Supplemental Statement of Disputed Material Facts (“Supplemental Statement”) as follows:

### **INTRODUCTORY STATEMENT**

West-Ward’s entitlement to summary judgment based on the Plaintiffs’ unclean hands is, as demonstrated in West-Ward’s Motion and supporting materials, based on the core facts that prove that the Plaintiffs engaged in the same behavior that they now contend is unlawful and forms the basis of a Lanham Act claim against West-Ward. The undisputed evidence demonstrates that: (i) Plaintiffs sold approximately 170,000,000 unapproved colchicine tablets between 1993 and 2006; (ii) in connection with such sales, Plaintiffs used the same Wholesaler Ordering Systems and Price Lists as West-Ward; (iii) the same information appeared on those databases for Mutual’s product and West-Ward’s product; (iv) Plaintiffs used the same package inserts as West-Ward in their unapproved colchicine; and (v) Plaintiffs’ unapproved tablets remained on certain Price Lists until 2009. (West-Ward’s Statement of Undisputed Material Facts (“SOF”) at ¶¶ 13-14, 16, 19-20 and 22-23 and Plaintiffs’ Responses thereto).<sup>1</sup> In short, the undisputed material facts show that Plaintiffs’ conduct with respect to the

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<sup>1</sup> A chart showing the central admissions made by the Plaintiffs is attached as Exhibit “A.”

sale of 0.6 mg. colchicine tablets was precisely the same as West-Ward's conduct about which the Plaintiffs' complain.

In this document, West-Ward responds to the supplemental factual assertions made by the Plaintiffs, but vigorously disputes that any of them have any material bearing on the grounds upon which West-Ward seeks summary judgment, or that any of them creates any material issue of fact that precludes the entry of summary judgment on the issue of unclean hands.

Responding to the individually numbered Paragraphs of Plaintiffs' Supplemental Statement, West-Ward states as follows:

1. West-Ward admits that no manufacturer had obtained FDA approval for single ingredient colchicine prior to 2009 and, to West-Ward's knowledge, Mutual had not yet discovered the specific safety information that it later published. Further answering Paragraph 1, West-Ward submits that these facts do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

2. West-Ward does not dispute the contents of Exhibits A, F and G to the Declaration of Nishan Kottahachchi, but disputes the Plaintiffs' characterization of the contents of the written documents. In particular, West-Ward does not agree that there was a "new drug safety initiative" in 2006. By statute, all "new" drugs have been required to have FDA approval since at least 1962. According to its

website, [www.fda.gov](http://www.fda.gov), the FDA took numerous enforcement actions against unapproved drugs prior to 2006.

3. West-Ward disputes that the Plaintiffs' actions were in response to the FDA guidance, but otherwise admits the assertions in Paragraph 3. Further answering Paragraph 3, West-Ward submits that the portion that it denied does not have any material bearing on its Motion and does not create a material issue of fact that would preclude the entry of summary judgment in its favor.

4. West-Ward is without sufficient knowledge or information to admit or deny the assertion in Paragraph 4, but is willing to accept them as true for purposes of the resolution of this Motion. Further answering Paragraph 4, West-Ward submits that assuming *arguendo* that Plaintiffs have not shipped or sold any unapproved colchicine products since July 2006, these assertions do not mean that Plaintiffs' unapproved colchicine tablets have not been listed on price lists and wholesaler ordering systems after that date in the same fashion as they were prior to 2006. (*See* SOF ¶ 23 and Plaintiffs' response thereto).

5. Admitted.

6. West-Ward is without sufficient knowledge or information to admit or deny the assertion in Paragraph 6, but is willing to accept them as true for purposes of the resolution of this Motion. Further answering Paragraph 6, West-Ward submits that, even if true, the assertions made in Paragraph 6 do not have any

material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

7. West-Ward is without sufficient knowledge or information to admit or deny the assertion in Paragraph 7, but is willing to accept them as true for purposes of the resolution of this Motion. Further answering Paragraph 7, West-Ward submits that, even if true, the assertions made in Paragraph 7 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

8. West-Ward is without sufficient knowledge or information to form a belief as to the truth of the factual assertions set forth in Paragraph 8. Further answering Paragraph 8, information pertaining to the potential health risks of colchicine appears to be the subject of expert testimony, rather than opinions offered by Plaintiffs' Senior Vice President of Business Development and Market Access and West-Ward states that the factual assertions made in Paragraph 8 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

9. West-Ward is without sufficient knowledge or information to form a belief as to the truth of the factual assertions set forth in Paragraph 9. Further answering Paragraph 9, West-Ward contends that the factual assertions in Paragraph 9 do not have any material bearing on its Motion and does not create a

material issue of fact that would preclude the entry of summary judgment in its favor.

10. West-Ward admits the assertions in the first sentence of Paragraph 10, but is without sufficient knowledge or information to form a belief as to the truth of the remaining factual assertions set forth in Paragraph 10. Further answering Paragraph 10, West-Ward states that the factual assertions in Paragraph 10 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

11. West-Ward denies the assertions contained in Paragraph 11. Further answering Paragraph 11, comparisons between the safety of various prescription drugs appear to be the subject of expert testimony, rather than opinions offered by Plaintiffs' Senior Vice President of Business Development and Market Access. West-Ward further states that the factual assertions that it denied in Paragraph 11 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

12. West-Ward denies the assertions in the first sentence of Paragraph 12. West-Ward admits the assertions in the second sentence of Paragraph 12. Further answering Paragraph 12, West-Ward states that the factual assertions in Paragraph 12 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

13. West-Ward admits the assertions in the first sentence of Paragraph 13, except that Plaintiffs' unapproved colchicine still appears to be available in the marketplace. West-Ward disputes the assertions in the second sentence of Paragraph 13, and states that the prescribing protocols utilized by Plaintiffs were the same as those currently used by Defendants West-Ward and Excellium. Further answering Paragraph 13, West-Ward states that the factual assertions in Paragraph 13 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

14. West-Ward admits that the FDA has issued warning letters to three manufacturers of unapproved colchicine, but relies upon the Court to review the wording and legal significance of those letters. Further answering Paragraph 14, West-Ward states that the factual assertions that it denied in Paragraph 14 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

15. Admitted.

16. West-Ward denies the assertions in the first sentence of Paragraph 16 on the grounds that, despite the Plaintiffs' vigorous campaign to get the FDA to remove West-Ward's unapproved product from the market -- which is amply demonstrated in the SOF and Plaintiffs' response thereto -- the FDA has not taken

action against West-Ward. West-Ward does not dispute that the FDA's website sets forth the matter included within the quotation marks in Paragraph 16 of the Plaintiffs' Supplemental Statement. The second sentence of Paragraph 16 is admitted. Further answering Paragraph 16, West-Ward states that the factual assertions that it denied in Paragraph 16 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

17. West-Ward admits that, for a variety of reasons, including expenses it incurred as a result of this litigation in 2009 and 2010, it raised the prices charged for its unapproved colchicine, but denies the remaining assertions contained in Paragraph 17. Further answering Paragraph 17, West-Ward states that the factual assertions that it denied in Paragraph 17 do not have any material bearing on its Motion and do not create a material issue of fact that would preclude the entry of summary judgment in its favor.

Respectfully submitted this 30<sup>th</sup> day of August 2010.

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# **EXHIBIT A**

**LIST OF KEY ADMITTED FACTS**

<b><u>Paragraph No. in SOF</u></b>	<b><u>Admitted Facts</u></b>
12	Mutual distributed more that 100,000,000 0.6 mg. colchicine tablets without FDA approval from 1993 until July 2006 in direct competition with West-Ward.
13	Mutual utilized the same Price Lists and Wholesaler Ordering Systems that it accuses West-Ward of using in the Complaint to market its unapproved colchicine tablets.
14	The Wholesaler Ordering Systems and Price Lists reported the same categories of information for Mutual's unapproved colchicine tablets that appear for West-Ward's tablets ( <i>i.e.</i> product name, strength, package size, label and its unapproved package insert, NDC number, pricing and manufacturer).
16	Between 1993 and 2006, Mutual distributed the same colchicine tablets that Defendants West-Ward and Excellium distributed, purchasing more than 170,000,000 colchicine tablets directly from West-Ward and Excellium for distribution under Mutual's own label, and using the same prescribing information, with the same safety and warning information provided with West-Ward's and Excellium's unapproved colchicine product.
18	In its Complaint, Mutual alleges that "relevant consumers are likely to mistakenly believe that the 'NR' or 'N/A' rating means that their unapproved colchicine products do not need to be approved by the FDA in order to be sold lawfully."
19	Just a few years prior to filing suit, Mutual provided the same "NR" rating for its unapproved colchicine products to McKesson, one of the country's largest wholesalers.
20	Mutual also stated on its own website that its unapproved colchicine tablets had an "NR" rating as recently as November 2006.

22	Mutual's unapproved colchicine tablets appeared on McKesson Corporation's Wholesaler Ordering System and Red Book's Price List until at least 2009.
23	As of July 7, 2010, Mutual's unapproved colchine tablets still appeared on the Medi-Span Price List, which still contained essentially the same information as reported for West-Ward's tablets, including the "NR" Therapeutic Equivalency Rating.
30	Immediately after submitting their NDA to the FDA—and prior to obtaining the FDA's approval—Plaintiffs began lobbying the FDA to take immediate action against distributors of unapproved colchicine tablets, including West-Ward.
34	Plaintiffs obtained FDA approval for their colchicine tablets, called Colcrys, on or about July 29, 2009 and immediately began distributing their product at a price of \$4.85 per tablet. The price for Colcrys was an approximately <u>5000%</u> increase in price from the \$.09 colchicine tablets that Mutual sold only a few years earlier.
42	In the months following the FDA's approval of Colcrys, Plaintiffs pressed the FDA to take immediate enforcement action against unapproved colchicine tablets.
43	Rather than wait for the FDA to take action against the distributors of unapproved colchicine, Plaintiffs initiated this lawsuit as their backup "legal strategy," seeking relief from the United States District Court for the Central District of California, the same district court in which a preliminary injunction in the <i>Ivax</i> case was granted.
44, 47-48	Plaintiffs filed an Emergency Motion for Preliminary Injunction in the present lawsuit against Defendants on September 11, 2009, seeking to enjoin Defendants from marketing, selling, and/or distributing their colchicine tablets. The California Court that adjudicated the motion found that "the evidence indicates that almost up to the moment they commenced this action, [Plaintiffs] were engaged in precisely the same activity over which they now seek to enjoin their competitors." The California Court concluded that "the

	doctrine of unclean hands substantially decreases the likelihood that Plaintiffs will ultimately prevail on the merits.”
50	In the days, weeks, and months after Plaintiffs’ Motion for Preliminary Injunction was denied, Plaintiffs sent another round of letters to the FDA, again urging the agency to take immediate enforcement action against unapproved colchicine tablets.